

Docket No.: 04-02 US

REMARKS**STATUS SUMMARY**

Claims 44-54 and 64-73 are pending in the present Application. Claims 44-54 and 64-73 stand rejected. In this Amendment, Applicant has amended claims 44, 46, 52-54, 64, 66 and 71-73.

EXAMINER INTERVIEW

Applicant thanks the Examiner for the time and consideration spent during a telephonic interview, which transpired on February 25, 2007, between the Examiner and Applicant's attorney David Gloekler. Independent claims 44 and 64 were discussed, as well as the references Shah et al. (U.S. Patent No. 3,801,280) and Zuellig et al. (U.S. Patent No. 6,126,904). It was agreed that Applicant would consider language other than "means for supporting" as regards claims 44 and 64.

Claim Rejections – 35 U.S.C. § 102

Claims 44-54 and 64-73 are rejected under 35 U.S.C. § 102(b) as being anticipated by Shah et al. (U.S. Patent No. 3,801,280).

To clarify the respective inventions being claimed, independent claim 44 has been amended to recite "a movable component including means for holding the implantable medical device in a container during movement of the movable component in the container." Similarly, independent claim 64 has been amended to recite "a movable component including means for holding the dosage form in a container during movement of the movable component in the container." Support for these amendments is found, for example, on page 9 of Applicant's specification. Applicant respectfully submits that neither claim 44 as amended nor claim 64 as amended reads on Shah et al.

An example of the invention recited in claim 44 or claim 64 is illustrated in Figure 1 and described on page 9 of Applicant's specification. In that example, a movable component (60) includes a holding means (64), which holds or retains an implantable medical device or a dosage form (14). It can be seen that as the holding means (64) is driven to movement within a

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container (30), the holding means (64) moves and the implantable medical device or dosage form (14) is agitated within the container (30) while being held by the holding means (64). The structure recited in claim 44 or claim 64 thus implements the non-contact agitation of a sample (here, an implantable medical device or dosage form) as described throughout the specification.

Shah et al. fails to teach these features. Referring to Fig. 2 of Shah et al., Shah et al. teaches a filter (8) attached to the end of a liquid conduit (34). The filter (8) consists of a base (9), a top (11), and cylindrical filter element (12) located therebetween. The filter element (12) surrounds a core (19) that is also located between the base (9) and the top (11). The core (19) is shaped to modify the path of liquid passing through the filter element (12) to the liquid conduit (34). These components making up the filter (8) rotate relative to a stationary, hollow rod (26) that is attached to the stationary liquid conduit (34). While the filter element (12) is rotating, particle-laden liquid is withdrawn through the filter element (12), and then through the hollow rod (26) and liquid conduit (34). The filter element (12) is merely a screen provided at the open end of the liquid conduit (34). Shah et al. fails to teach any means for configuring the filter element (12) so as to hold an implantable medical device or a dosage form. Neither the filter element (12) nor any other movable part of the filter (8) holds any object while the filter element (12) moves in the container.

Shah et al. teaches an entirely different approach to sample dissolution. The only structure arguably suitable for holding a dosage form in Shah et al. is a conventional wire basket (2) also illustrated in Fig. 2 of Shah et al. The basket (2) is separate and distant from, and not part of, the filter (8). The basket (2) does not move in the container. A dosage form, when provided by Shah et al, is separately contained within the basket (2). A dosage form contained within the basket (2) dissolves into particles into the media, the particles then flow through the media, passes through the filter (8), and flow out from the container via the hollow rod (26) and liquid conduit (34).

In fact, Shah et al. expressly teaches that it is disadvantageous to utilize a moving dosage form holder (such as a wire basket) and a stationary filter. *See* Shah et al., col. 1, lines 47-67. Shah et al.'s answer is to do the opposite: maintain a dosage form holder such as the basket (2) stationary and, instead, rotate the filter element (12) for a number of reasons specified in col. 2 generally and col. 3, lines 47-57. In fact, Shah et al. teaches to move the filter element (12) to

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prevent clogging. That is, the filter element (12) in Shah et al. is specifically configured so as *not* to be capable of holding or retaining anything. *See, e.g.*, Shah et al, at col. 7, lines 30-39, as well as the passages cited above.

In contrast to the teaching of Shah et al., the holding means recited in claim 44 or 64 is configured to hold or retain an implantable medical device or a dosage form in a container and to do so while the holding means is being driven to move in the container. Applicant's teaching of non-contact actuation of an implantable medical device or a dosage form is not found in the prior art of record.

In view of the foregoing, Applicant respectfully submits that amended claims 44 and 64, and claims 45-54 and 65-73 at least by way of dependency, are patentable over all prior art of record, and therefore respectfully requests favorable reconsideration and allowance of claims 44-54 and 64-73.

Item 3 on page 2 of the above-identified Office Action indicates that claims 44-46, 49-54, 64-66 and 68-73 are rejected under 35 U.S.C. § 102(b) as being anticipated by Shah et al. In view of the rejection to claims 44-46 and 64-73 discussed above and the previous Office Action mailed August 7, 2007, Applicant believes that this rejection actually pertains to Zuellig et al. (U.S. Patent No. 6,126,904) and will respond accordingly.

The clarifying amendments made to independent claims 44 and 64 and 64-73 are discussed above. Zuellig et al. likewise fails to teach these features. Referring to Figs. 1B and 1C of Zuellig et al., Zuellig et al. merely teaches magnetic objects (35) of various shapes utilized as an agitation element (i.e., a magnetically actuated stir bar) in a container. No means are provided for holding an implantable medical device or a dosage form. Any contact of the magnetic object (35) with another object would be a transient condition. Zuellig et al. provides no teaching for configuring the magnetic object (35) to hold anything, but only to agitate the surrounding media.

In view of the foregoing, Applicant respectfully submits that amended claims 44-54 and 64-73 are patentable over all prior art of record, and therefore respectfully requests favorable reconsideration and allowance of claims 44-54 and 64-73.

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CENTRAL FAX CENTER****FEB 28 2008****Docket No.: 04-02 US****CONCLUSION**

In light of the above amendments and remarks, it is respectfully submitted that the present application is now in proper condition for allowance, and an early notice to such effect is earnestly solicited. However, if the Examiner believes that the Amendments and Remarks do not place the application in condition for allowance, Applicant respectfully requests that an Advisory Action be mailed at the earliest possible date.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters.

Respectfully submitted,

Date:

2/28/08

By:

David P. Gloekler

David P. Gloekler
Registration No. 41,037
Attorney for Applicant
Phone: (919) 313-6163
Fax: (919) 313-6170

CORRESPONDENCE ADDRESS:

Ms. Bella Fishman
Varian, Inc.
3120 Hansen Way, M/S D-102
Palo Alto, CA 94304-1030
650.424.4814
bella.fishman@varianinc.com
Varian Reference No. 04-05 US
Customer No. 23693